SUMMARY:

Renew the Food and Drug Administration, Advisory Committee; Science Board to

[Docket No. FDA–2016–N–0001]

For further information contact:

Jeffrey M. Zirger,

[FR Doc. 2016–17170 Filed 7–20–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Notice; renewal of advisory committee]

Agency: Food and Drug Administration, HHS.

Action: Notice; renewal of advisory committee.

Summary: The Food and Drug Administration (FDA) is announcing the renewal of the Science Board to the Food and Drug Administration by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Science Board to the Food and Drug Administration for an additional 2 years beyond the charter expiration date. The new charter will be in effect until June 26, 2018.

Dates: Authority for the Science Board to the Food and Drug Administration will expire on June 26, 2018, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Rakesh Raghuwanshi, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, Bldg. 1, Rm. 3309, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4769, rakesh.raghuwanshi@fda.hhs.gov.

Supplementary information: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Science Board to the Food and Drug Administration. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Science Board advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility. The Science Board shall provide advice to the Commissioner and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board will provide advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science; and input into the Agency’s research agenda; and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.

The Committee shall consist of a core of 21 voting members including a Chair and Co-Chair. The members, Chair and Co-Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of food science, safety, and nutrition; chemistry; pharmacology; translational and clinical medicine and research; toxicology; biostatistics; medical devices; imaging; robotics; cell and tissue based products; regenerative medicine; public health and epidemiology; international health and regulation; product safety; product manufacturing sciences and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products. Members
will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Committee may also include technically qualified federal members.

Further information regarding the most recent charter and other information can be found at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm115356.htm or by contacting the Designated Federal Officer (see FOR FURTHER INFORMATION CONTACT). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at http://www.fda.gov/AdvisoryCommittees/default.htm.

Dated: July 15, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–17182 Filed 7–20–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft revised guidance for industry #3 entitled “General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals.” This draft revised guidance describes the type of information that FDA’s Center for Veterinary Medicine (CVM) recommends sponsors provide to address the human food safety of new animal drugs used in food-producing animals.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 19, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions
Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2005–D–0155 for “General Principles for Evaluating the Human Food Safety of New Animal Drugs used in Food-Producing Animals.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.